

Congress of the United States
House of Representatives
Washington, DC 20515-4702

Testimony of Congressman Jack Metcalf
Before Hearing of Committee on Government Reform
October 3, 2000

Mr Chairman, I want to thank you for inviting me to testify today on the potential relationship between Gulf War Illnesses and the anthrax vaccinations. I share the gratitude of many veterans and military personnel across this nation for your determined insistence that our men and women in uniform be provided the best in force protection.

I want to make it clear to this committee that when I began this investigation in 1997, I did so in response to the concerns of veterans and their families who had heard that antibodies to squalene had been discovered in the blood of some sick Gulf War-era veterans. My office was assured by other congressional staff that there was nothing to the allegations. It seemed prudent to me to have GAO take a look at the issue, and put it to rest. However, after an investigation that was greatly delayed by a stunning lack of cooperation, we find ourselves with only more questions, and few answers. We must get to the truth.

Indeed, we have an obligation to pursue the truth, wherever it may lead us. To do less would be to act dishonorably toward the dedicated men and women who stand between us and a still dangerous world.

For that reason, I have issued a report culminating a three year investigation into the conduct of the DOD (Department of Defense) with regard to **the possibility that squalene, a substance in vaccine adjuvant formulations not approved by the FDA, was used in inoculations given to Gulf War era service personnel.** According to the GAO (General Accounting Office), scientists have expressed safety concerns regarding the use of novel adjuvant formulations in vaccines, including squalene.

The report reveals that **the FDA has found trace amounts of squalene in the anthrax vaccine. The amounts recorded could "boost immune response,"** according to immunology professor Dr. Dorothy Lewis of Baylor University. Mr. Chairman, I was shocked to learn this week that a FDA spokesperson had dismissed their own findings by declaring that the levels found are inconsequential, that they are naturally occurring, and that one would expect to find these levels in any biological vaccine. We've been told for three years there is no squalene in the anthrax vaccine, then suddenly we are told, "Oh yes, its there, but its no big deal-- its everywhere." The questions must be asked: Have they indeed tested all vaccines for the presence of squalene? If so, at what levels has squalene been detected? Does that mean the FDA would expect to find squalene in childhood vaccines? If detected, could the levels harm a three month old?"

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For years we have been told by the Department of Defense, as the FDA sat by in silent complicity, that they had tested for the presence of squalene and that the anthrax vaccine was found to contain no squalene. Indeed they have stated repeatedly, "the FDA verified that none of the vaccines used during the Gulf War contained squalene as an adjuvant." However, on the first page of the letter sent to me by the FDA, they corrected the DOD remark by clarifying that, "neither the licensed vaccines known to be used in the Gulf War, nor the one investigational product known to have been used, contained squalene as an adjuvant in the formulations on file with FDA." Those are two very different statements of the facts.

Therefore, I am calling on you, Mr. Chairman, to initiate an immediate GAO investigation that must ask one vital question: How did squalene get into the anthrax vaccine tested by the FDA? Scientists who have reviewed my staff's findings, agree that this question must be answered.

My report states that an aggressive investigation must be undertaken to determine the source of the squalene, and the potential health consequences to those who have been vaccinated, both during and after the Gulf War. It again calls for an immediate halt to the current Anthrax Vaccination Immunization Program until this issue and the other problems so clearly defined by this committee have been resolved.

My report also documents at length DOD "stonewalling" attempts to resolve the squalene issue, which **led GAO investigators to document their concerns questioning "a pattern of deception."** The GAO stated the DOD denied conducting extensive squalene testing before the Gulf War, then admitted it after being confronted with the public record. The GAO revealed that some DOD officials deliberating deployment of the anthrax vaccine expressed a "willingness to jump out and use everything," in discussing experimental vaccines containing adjuvants not approved by the FDA.

GAO also found that Peter Collis, DOD official who headed vaccine efforts, refused to cooperate with them. The report states that the DOD has refused to act in good faith upon the GAO recommendation to replicate the findings of a test developed by renowned virologist Dr. Robert Garry of Tulane University, although DOD admitted they could easily do so. The work of the Tulane researchers has been peer-reviewed in a scientific publication of high standing.

Finally, my report states that "Congress should take immediate action to review the findings of the GAO and the Armed Services Epidemiological Board, and provide independent oversight for the immediate implementation of their recommendations." **The board recently called on the DOD**

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to engage in close cooperation with the Tulane researchers, mirroring the GAO recommendations from March of 1999. How tragic that we have lost nearly two years because the DOD insisted on having their adjuvant expert, who lied to the GAO about his role during the Gulf War, try to re-invent the wheel instead of cooperating with the Tulane researchers as directed. They have repeatedly expressed their willingness to help find answers for those who are suffering from Gulf War Illnesses. I ask this committee to insure the recommendations are implemented by those who will guard the integrity of the process and get to the truth.

Mr. Chairman, I want to once again commend you for your courage and leadership. As I am about to leave the Congress, I ask you and the committee to stay the course until the truth is determined and justice is done. Veterans, active service members and their families deployed around the world are counting on you. Thank you so much.